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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,035	12/11/2000	Jas C. Lang	22727/04078	9153

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,035

Applicant(s)

LANG, JAS C.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/8/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claim 1 has been amended.
Claims 2-22 have been canceled.
Claims 23-28 have been added.
2. Claims 1, 23-28 are under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
4. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

5. The rejection of claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
6. The rejection of claims 4-5 are rejected under 35 U.S.C. ' 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims.
7. The rejection of claims 1-2, 4-5, 9, 21 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.

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8. The rejection of claims 1-5, 9, 21 under 35 U.S.C. 102(e) as being anticipated by Baker et al (US patent application publication US 2003/0073129, with priority to at least 10/98) is withdrawn in view of the amendments to the claims.

9. The rejection of claim 21 under 35 U.S.C. 102(b) as being anticipated by The 1991 Boehringer Mannheim Biochemical Catalog, page 557 is withdrawn in view of the amended claims.

Response to Arguments

10. The rejection of claim 1, and newly added claims 23-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

This is a written description rejection.

The response filed 10/01/04 has been carefully considered but is deemed not to be persuasive. The response states that the claims are described for example by Examples 1, 2, 3, and 5 and in the example lower expression of the DESC1 is seen in cancerous tissue compared to normal (see page 4 of response). In response to this argument, the specification does not teach the DESC1 "gene" as stated in the previous office action. The term "gene" encompasses introns and control elements and the specification does not teach these elements. In addition, the term DECS1" encompasses variants and the specification does not teach such variants.

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The following are NEW GROUNDS of rejection

11. Claims 1, 23-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of squamous cell carcinoma and prostate cancer in a subject comprising providing a tissue sample suspected of having cancer from the subject of head, neck, or prostate and assaying for the presence of SEQ ID NO:1 or 3 using a sequence of 626-1321 of SEQ ID NO:1 or 3 or SEQ ID NO:5, 6, 7, 8, 9, and 10, wherein a reduced expression of SEQ ID NO:1 or 3 in the sample compared to a normal match sample is indicative of said cancer, does not reasonably provide enablement for a method of detecting just any DESC1 expression by using just any nucleic acid and wherein a reduced expression is indicative when the sample is not compared to a control sample. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to detecting the expression of any DESC1 gene using just any nucleic acid and wherein a reduced expression when not compared to

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any normal tissue is indicative of cancer. The specification discloses that SEQ ID NO:1 or 3 are not expressed in carcinomas and prostate and expressed in normal tissue (see page 15 and Figure 3A). The specification discloses that SEQ ID NO:1 and 3 are the DESC1 cDNA and reduced expression in squamous cell carcinoma (see example 1) and in prostate cells (see example 5). The specification does not teach detection of SEQ ID NO:1 or 3 with just any DNA or reduced expression when not correlated to a control sample.

It is well known in the art that one would need to use the cDNA of the entire SEQ ID NO:1 or 3 from the coding region or a probe from the coding region to detect the expression of the DESC1. In addition, one skill in the art would know that not just any nucleic acid, as encompassed by claims 1, 23-25, would or could be used for detection of the DESC1 expression. In addition, one skill in the art would also know that one would have to compare the expression levels of the sample to a control in order to determine if there were a reduced expression.

In view of the lack of guidance, lack of examples, and lack of predictability in the art as evidenced from the above discussion, one skilled in the art would be forced into undue experimentation in order to practice the broadly claimed invention.

Claim Rejections - 35 USC § 112

12. Claims 1, 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 1, 23-28 are indefinite for reciting "wherein reduced DESC1 expression" because it is not clear what the reduction is compared to. Is the reduction compared to a matched sample or a control sample from another patient or a sample of one tissue compared of one source to a different source, i.e. a skin sample and a liver sample?

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is ~~703-872-~~

~~9306~~ 571 273 8300

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER